UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

BARBARA KAISER and ANTON KAISER,	)	
Plaintiffs,	)	
v.	)	CAUSE NO. 2:17-CV-114-PPS
JOHNSON & JOHNSON and ETHICON INC.,	)	
Defendants.	)	

OPINION AND ORDER

Prior to the trial of this matter, I heard oral argument on various motions *in limine* filed by the Parties. At the hearing, I denied Ethicon's Motion to Admit FDA Evidence, DE 248, and granted and the Kaisers' mirror image motion to exclude FDA evidence, DE 244. I provided a detailed explanation from the bench on the reasons for those rulings, but I also told the Parties that a written opinion would follow. [DE 276 at 34-40.] This is that opinion.

While this case was before him as part of the MDL, Judge Goodwin excluded evidence regarding the FDA's §510(k) clearance process. [*See, e.g.*, DE 146.] Judge Goodwin explained:

> I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these case[sic], a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process

> does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**.

[*Id.*]

The issue of the admissibility of FDA §510(k) evidence was reanimated before me because the Indiana Product Liability Act provides a rebuttable presumption that a product is not defective, and the manufacturer is not negligent, where the product complied with applicable codes, standards, regulations, or specification. *See* Ind. Code § 34-20-5-1. Ethicon argues that evidence regarding the fact that Prolift was cleared for marketing through §501(k) review was relevant to this litigation because of the IPLA's rebuttable presumption and, in fact, mandated application of the presumption to this case.

Before I explain why I agree with Judge Goodwin, and the majority of the other courts that have addressed this issue, some background on the §510(k) process is necessary. The §510(k) review process originates from the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act. The MDA was enacted in order to "impose[ ] a regime of detailed federal oversight" of medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Under the MDA, certain

devices must complete a thorough premarket approval (PMA) process with the FDA before they may be marketed, including all devices that cannot "provide reasonable assurance of [their] safety and effectiveness" under less stringent scrutiny, and that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "present[ ] a potential unreasonable risk of illness or injury." *Id.* at 317; 21 U.S.C. § 360c(a)(1)(C). The PMA process requires the applicant to demonstrate a "reasonable assurance" that the device is both "safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001) (quoting 21 U.S.C. § 360e(d)(2)(A), (B)).

However, an exception to the PMA requirement exists for medical devices that were already on the market prior to the MDA's enactment in 1976; these devices are allowed to remain on the market until the FDA initiates and completes PMA review for them. *See* 21 U.S.C. § 360e(b)(1)(A); *Buckman*, 531 U.S. at 345. In addition, to prevent the monopolistic power that this exception might bestow on the manufacturer of the predicate device, the MDA also allows other manufacturers to piggyback on earlier products by allowing them to market devices that are shown to be "substantially equivalent" to pre–1976 devices that are exempt from the PMA requirement. *Buckman*, 531 U.S. at 345; 21 U.S.C. § 360e(b)(1)(B)). The §510(k) process is the method by which a manufacturer demonstrates substantial equivalence. *Id.*

While the MDA provided this initial framework, the Safe Medical Devices Act of 1990 provided firmer footing for this loosely designed process. The SMDA finally codified the definition of substantial equivalence that the FDA had developed administratively through the experience of clearing devices for the 14 years since the enactment of the MDA. *See* 21 U.S.C. §360c(i). In addition, the SMDA ended the legal necessity to cite a pre-MDA predicate device, so that devices cleared after the enactment of the MDA could be used as predicates without construction of a clearance chain back to a pre-MDA predicate device. *See* 21 U.S.C. §360c(f). While this allowed the state of the art to evolve more freely, it created a more tangential relationship between FDA clearance and the safety-focused PMA process.

Returning to the case at hand, in September 2007, Ethicon submitted its §510(k) notice to the FDA for Prolift. [DE 248-4.] The FDA found Prolift "substantially equivalent . . . to legally marketed predicated devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act that do not require approval of a premarket approval application," classifying Prolift as a Class II device and clearing it to proceed to market in May 2008. [DE 248-5.] The notice explicitly stated that "FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." [*Id.*]

Ethicon argues that evidence of this clearance is relevant to this action because it entitles Ethicon to the rebuttable presumption found in Ind. Code § 34-20-5-1. I disagree. Indiana Code § 34-20-5-1 provides:

> In a product liability action, there is a rebuttable presumption that the product that caused the physical harm was not defective and that the manufacturer or seller of the product was not negligent if, before the sale by the manufacturer, the product:
>
> (1) was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, and labeled; or
>
> (2) complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana.

This presumption has been interpreted narrowly. While it is clear from its wording that the first part of the presumption relates to safety of the product, the Indiana Court of Appeals has explicitly found that in order "for evidence of compliance with governmental standards to be relevant, the standard itself must relate to the risk or product defect at issue." *Wade v. Terex-Telect. Inc.*, 966 N.E.2d 186, 194 (Ind. Ct. App. 2012); *see also Rogers ex rel. Rogers v. Cosco, Inc.*, 737 N.E.2d 1158, 1163 (Ind. Ct. App. 2000) (finding that compliance a Federal Motor Vehicle Safety Standard warranted the application of the presumption, which the plaintiff then needed to rebut to succeed on her claims under the IPLA). This makes sense, logically, given that whether a product is defective under the IPLA turns on whether it is "unreasonably dangerous" to any

user or consumer. *See* Ind. Code 34-20-2-1. As such, for the presumption to apply in this case, Ethicon would have to show that the standard with which it conformed or complied—the §510(k) process—spoke to safety. The problem for Ethicon, as shown below, is that the §510(k) process speaks to equivalency, not safety.

While it may seem counterintuitive that this aspect of the FDA's clearance process does not speak to the safety of the device, that is the generally accepted interpretation of the §510(k) process by courts in this country. This includes those courts handling cases in states with rebuttable presumptions. *See, e.g.*, *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304 (11th Cir. 2017) (applying Florida law); *Tingey v. Radionics*, No. 04-4216, 193 Fed. App'x 747, 755, 2006 WL 2258872, at *6 (10th Cir. Aug. 8, 2006) (applying Utah law)*; Adams et al. v. Boston Scientific Corp.*, 177 F. Supp. 3d 959 (S.D. W. Va. 2016) (applying Texas law)*; Williams v. Boston Scientific Corp.*, No. 2:12-CV-02052, 2016 WL 1448860, at *3 (S.D. W. Va. Apr. 12, 2016) (applying Wisconsin law); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 761 (S.D. W. Va. 2014) (applying Texas law).

It all starts with *Meditronic, Inc. v. Lohr*, 518 U.S. 470, 492 (1996), where the United States Supreme Court explained that "the §510(k) process is focused on *equivalence*, not safety" and the design of the device "has never been formally reviewed under the MDA for safety or efficacy." *Id.* at 493. As the Court explained, "substantial equivalence determinations provide little protection to the public. These determinations simply compare a post–1976 device to a pre–1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier

device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective." *Id.*

The §510(k) process is a cursory one when compared to the strenuous PMA review. To illustrate this point, in *Lohr*, the Supreme Court noted that "[i]n contrast to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in an average of only 20 hours. As one commentator noted: 'The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.'" *Id.* at 479 (quoting Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court expanded on its analysis in *Lohr*. The Court explained that the PMA process "*is* federal safety review," as opposed to §510(k) review, which is a test for substantial equivalence. *Id.* at 323. As the Court explained, "[w]hile §510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence." *Id.* (quotations marks and citations omitted).

This is a distinction with a difference as it relates to this case because, as I discussed above, for the IPLA presumption to apply, the standard with which Prolift conformed or complied must speak to safety. Because §510(k) is focused on

equivalency and not safety, it is not relevant to the application of the presumption in this case and does not mandate its application.

Furthermore, under Federal Rule of Evidence 403, a court may "exclude relevant evidence if its probative value is substantially outweighed" by the danger of, among other things, confusing the issues, misleading the jury, and wasting time. I agree with Judge Goodwin that the §510(k) evidence does not speak directly to safety and efficacy and, therefore, is of very little probative value. I believe that introduction of evidence regarding the §510(k) process potentially would have confused the jurors regarding the meaning and importance of §510(k) clearance, possibly resulting in the jurors erroneously concluding that §510(k) clearance proved safety.

What's more, the trial would have been completely sidetracked with the introduction of the FDA evidence. If the evidence regarding Prolift's §510(k) clearance had been admitted into evidence, almost assuredly, Prolift's *whole* FDA story would have been told to the jury, including evidence that after the Prolift device was marketed, it later received FDA scrutiny and was subsequently removed from the market after a series of exchanges with the FDA regarding its safety. This would require the introduction of additional evidence and testimony from regulatory experts and Ethicon employees. When balancing the probative value of the evidence against these dangers and the needless consumption of time, I find that excluding the evidence is appropriate.

Conclusion

For the reasons discussed above, and at the hearing held on November 28, 2017, Ethicon's Motion to Admit FDA Evidence, DE 248, is **DENIED** and the Kaisers' Motion in Limine to Exclude FDA §510(k) evidence, DE 244, is **GRANTED.**

SO ORDERED.

ENTERED: March 16, 2018.

s/ Philip P. Simon
PHILIP P. SIMON, JUDGE
UNITED STATES DISTRICT COURT